

REMARKS

Applicant respectfully requests reconsideration of the application in view of the following remarks.

Claims 1-4 and 6-14 remain pending and are not amended.

The Office Action maintains the obviousness rejections for the reasons set forth at pages 2-16 of the Office Action. Applicant respectfully traverses.

Pages 12-16 of the Office Action explain why the obviousness rejections are maintained over the evidence of non-obviousness provided in the Rule 132 Declaration of Dr. Hilt. A review of the Examiner's "Response to Arguments" indicates that the Examiner is relying on her own interpretations of the cited references and state of the art, in contradiction to the testimony provided by Dr. Hilt.

For example, even though Dr. Hilt explained the fallacy of any motivation to use 4-OHT based on its characterization as an "active metabolite" of tamoxifen, *see, e.g.*, Hilt Declaration, ¶¶ 8-13, the Examiner still alleges that "it would have been obvious . . . to administer 4-OHT in a method of treatment of mastalgia because 4-OHT is known to be an active metabolite . . . of tamoxifen," Office Action, page 12. Moreover, Dr. Hilt provided detailed testimony on the unpredictability of the activity of SERMs, *see, e.g.*, Hilt Declaration, ¶¶ 15, 19-22 & 24, and explained why the cited teachings of Mauvais-Jarvis do not provide any reasonable expectation of success, *see, e.g.*, Hilt Declaration, ¶¶ 27-28 & 30-31. Yet, the Examiner still asserts that "[i]t would have been obvious from the teachings of [Mauvais-Jarvis] that benign breast diseases can be treated with . . . 4-OHT." Office Action, pages 15-16. The Examiner's treatment of the evidence provided in the Hilt Declaration is contrary to MPEP § 2145, which requires Examiners to consider and give appropriate weight to all evidence of non-obviousness.

The basis of the obviousness rejection appears to be that the cited references would have "motivate[d] a person of ordinary skill in the art to use 4-OHT in a method of treatment of benign breast disease," *e.g.*, that it would have been "obvious to try" 4-OHT in the recited methods. Although the Supreme Court in *KSR* stated that, in some circumstances, an

invention that was “obvious to try” may be obvious under §103, the present case does not present such circumstances. As noted in MPEP § 2145, an “‘obvious to try’ rationale may support a conclusion that a claim would have been obvious where one skilled in the art is choosing from *a finite number of identified, predictable solutions, with a reasonable expectation of success.*” MPEP § 2145 (citing *KSR*) (emphasis added). Assuming for the sake of argument only that active metabolites of tamoxifen represent “a finite number of identified [possible] solutions” for the treatment of mastalgia, the evidence of record, including the Hilt Declaration, demonstrates that those possible solutions are not predictable, and that there was no reasonable expectation of success in being able to use 4-OHT to treat mastalgia, as recited in the instant claims. Thus, neither the MPEP nor *KSR* itself support application of the “obvious to try” standard to the present invention.

For at least the foregoing reasons, Applicant respectfully requests reconsideration and withdrawal of the §103 rejections.

Conclusion

Applicant believes that the application is in condition for allowance, and an early notice to that effect is earnestly solicited.

Should there be any questions regarding this application, or should any issue remain, the Examiner is invited to contact the undersigned by telephone in order to advance prosecution.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check or credit card payment form being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

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